

In the European Community:

**BODYGUARDIAN™ MINI**

**BODYGUARDIAN™ MINI**

**Procedure Pack**

# Instructions for Use



## **FULLY WATERPROOF**

Featuring a waterproof monitor safe for showering, bathing, and submerging in water as deep as 3 feet.

The assembler's declaration of conformity is available at:

2900 37<sup>th</sup> Street NW  
Building 003  
Rochester, MN 55901  
USA

CONFIDENTIAL AND PROPRIETARY

The information contained in this document is confidential and proprietary to Boston Scientific Cardiac Diagnostic Technologies, Inc. This document may not be disclosed, copied, or distributed in any form to any third party without written permission of Boston Scientific Cardiac Diagnostic Technologies, Inc.

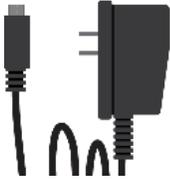
Copyright © Boston Scientific Cardiac Diagnostic Technologies, Inc.  
May 2024  
All rights reserved.  
LA1021-A LL-60054-M

## Table of Contents

Equipment included in Pack.....	1
Indications for Use / Intended Purpose.....	2
BodyGuardian Mini Procedure Pack.....	2
BodyGuardian Mini Monitor .....	2
Patientcare Platform.....	3
Patientcare Link.....	3
BodyGuardian Mini Bridge .....	3
BodyGuardian Mini Slide Strip .....	3
Did you receive Strips, a Bridge, or an ECG lead set? .....	4
Getting started (using Strips).....	5
1 Prepare your skin.....	5
2 Attach the monitor to the Strip .....	5
3 Attach to your chest .....	6
Preferred chest placement (vertical).....	8
Alternate placement (horizontal).....	9
4 Turn on monitor .....	10
Getting started (using a Bridge).....	11
1 Prepare your skin.....	11
2 Snap the ECG electrodes to the Bridge.....	12
3 Attach the monitor to the Bridge.....	12
4 Attach to your chest .....	13
Preferred chest placement (vertical).....	14
Alternate placement (horizontal).....	15
5 Turn on monitor .....	16
Getting started (using an ECG lead set) .....	17
1 Prepare your skin.....	17
2 Attach the monitor and the ECG electrodes .....	18
3 Attach to your chest .....	18
EU chest placements .....	19
4 Turn on monitor .....	20
Recording symptoms .....	21
Charging the monitor .....	22
Charging time.....	22
Replacing the Strip .....	23
Replace the ECG electrodes (for Bridge or ECG lead set).....	23
Water resistance.....	23
Air travel.....	24
Cleaning the monitor.....	24
Exterior casing .....	24
USB port.....	24
Required materials.....	24
Cleaning the USB port.....	25
If the monitor starts beeping during your monitoring session .....	26
2 beeps and 2 red flashes every 5 seconds .....	26
2 beeps and 2 blue flashes every 5 seconds .....	26
Monitor indicators.....	27
Contraindications .....	28
System Level .....	28
Warnings .....	28
System Level .....	28
BodyGuardian Mini Monitor .....	28
General safety precautions.....	29

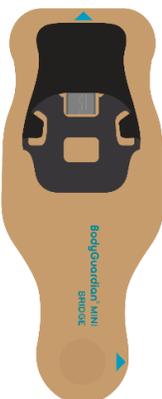
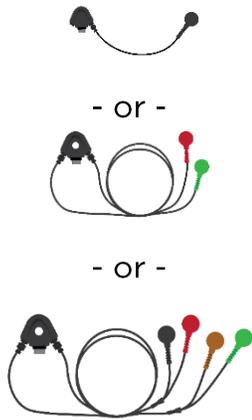
System Level .....29  
BodyGuardian Mini Monitor .....29  
Appendix A: Symbols .....30  
Appendix B: Technical specifications .....32  
Appendix C: Electromagnetic Emission .....32  
Appendix D: Immunity Test Levels Phenomenon.....33

## Equipment included in Pack \*

<p><b>BodyGuardian Mini monitor</b></p>  <p><b>NOTE:</b> For the purposes of this IFU, <i>Mini monitor</i> refers to the BodyGuardian Mini or the BodyGuardian Mini EL monitor.</p>	<p><b>charging cord</b></p>  <p>(equipment may differ from pictured)</p>
--	---

### OPTIONAL EQUIPMENT

Your equipment will include either **Strips, a Bridge (with electrodes), or ECG lead set (with electrodes)**. You will not receive all three. Follow the instructions for the equipment you receive.

<p><b>BodyGuardian Mini Slide Strip</b></p>  <p><b>CE</b></p> <p>- and - <b>saline wipes</b></p>  <p>(only included with Strips)</p>	<p><b>BodyGuardian Mini Bridge</b></p>  <p><b>CE</b></p> <p>- and -</p> <p><b>ECG electrodes ***</b></p>  <p><b>CE</b></p>	<p><b>ECG lead set types **</b></p>  <p>- or -</p> <p>- or -</p> <p>- and -</p> <p><b>ECG electrodes</b></p>  <p><b>CE</b></p>
---	---	---

\* For more information on components of the system that are not included in the pack, see **page 35**.  
 \*\* Registered as an accessory to the sensor under CE 0537.  
 \*\*\* Compatible electrode types with the Bridge:  
MANUFACTURER      MODEL / NAME  
 Covidien                      Kendall 455 Standard ECG



Do not use your own personal device chargers. Only use the charger(s) provided to charge Boston Scientific Cardiac Diagnostics devices.

## Indications for Use / Intended Purpose

### BodyGuardian Mini Procedure Pack

The BodyGuardian™ Remote Monitoring System is intended to be used as patient biometric monitoring systems. The BodyGuardian Mini procedure pack consists of an ECG monitor, various software devices and accessories that can be used to observe a wide variety of patient conditions (e.g., non-lethal cardiac arrhythmias, sinus bradycardia and sinus tachycardia) and parameters (e.g., activity, weight, blood pressure, and oxygen level) as prescribed by the healthcare provider.

#### Important

- BodyGuardian Mini (in the EU called BodyGuardian Mini Procedure Pack) does not summon physicians nor emergency assistance and does not replace direct communication with your health care provider. **If you are experiencing a medical emergency, dial emergency assistance (911 US, 112 EU).**
- If you have questions or encounter problems while you are using BodyGuardian Mini (in the EU called BodyGuardian Mini Procedure Pack), contact your health care provider.
- For a complete list of indications, contraindications, and warnings, see **pages 28-29**.

### BodyGuardian Mini Monitor

The BodyGuardian Mini is intended for use in clinical long-term ambulatory ECG monitoring, data transfer and analysis. BodyGuardian Mini is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments. BodyGuardian Mini provides the detection and reporting features appropriate for the indications below:

- Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmias.
- Evaluation of patients for ST segment changes
- Evaluation of patients with a pacemaker
- Evaluation of patient rest and stress ECG
- Reporting of heart rate variability analysis
- Wireless transmission of patient ECG data and arrhythmia events for further analysis.

Interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The BodyGuardian Mini does not provide interpretive statements. BodyGuardian Mini is contraindicated for:

- Those patients requiring attended, in-hospital monitoring for life threatening arrhythmias
- Pediatric patients weighing less than 10 kg

## **Patientcare Platform**

The PatientCare Platform is intended for use by qualified healthcare professionals for the monitoring assessment of the indicated patient populations for biometric measures including arrhythmias using ECG data. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, cardiac event monitor, mobile cardiac telemetry in 1-3 channels, or other similar devices when assessment of the rhythm is necessary. The PatientCare Platform provides ECG signal processing and analysis, QRS and Ectopic Beat detection, interval measurement, heart rate measurement, and rhythm analysis. The PatientCare Platform is not for use in life supporting or sustaining systems. PatientCare Platform interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

## **Patientcare Link**

The PatientCare Platform is a set of databases and functions, stored procedures, and applications that run as a continuous service on commercially available off-the-shelf computing resources. PatientCare Link, an extension of PatientCare Platform, is a Windows-based utility downloaded from the PatientCare Platform cloud-based server application and runs on a workstation intended to directly send data to the PatientCare Platform software. PatientCare Link reads data from a BodyGuardian Mini device, transforms the data into the format accepted by the PatientCare Platform application programming interfaces (APIs), and sends the data via those APIs.

## **BodyGuardian Mini Bridge**

The Bridge is intended to serve as an interface to transmit physiological signals from body-adhering standard electrodes to the ECG monitor. The Bridge is optionally included in the procedure pack.

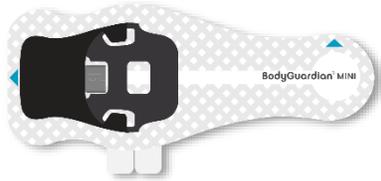
## **BodyGuardian Mini Slide Strip**

The Mini Slide Strip is intended to transfer patient physiological data to the connected ECG monitor. The Mini Slide Strip includes saline wipes. The Mini Slide Strip is optionally included in the procedure pack.

## Did you receive Strips, a Bridge, or an ECG lead set?

Your equipment will include either Strips, a Bridge (with electrodes), or an ECG lead set (with electrodes). You will not receive all three. Follow the instructions for the equipment you receive.

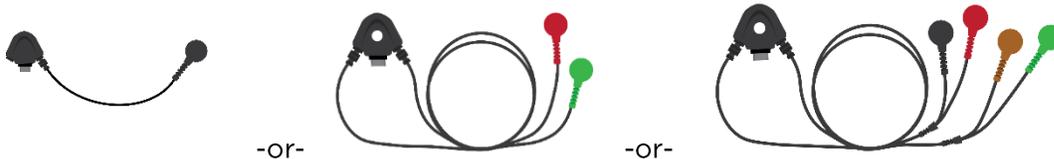
- If your equipment came with Strips, see page 5.



- If your equipment came with a Bridge, see page 11.



- If your equipment came with an ECG lead set, see page 17.



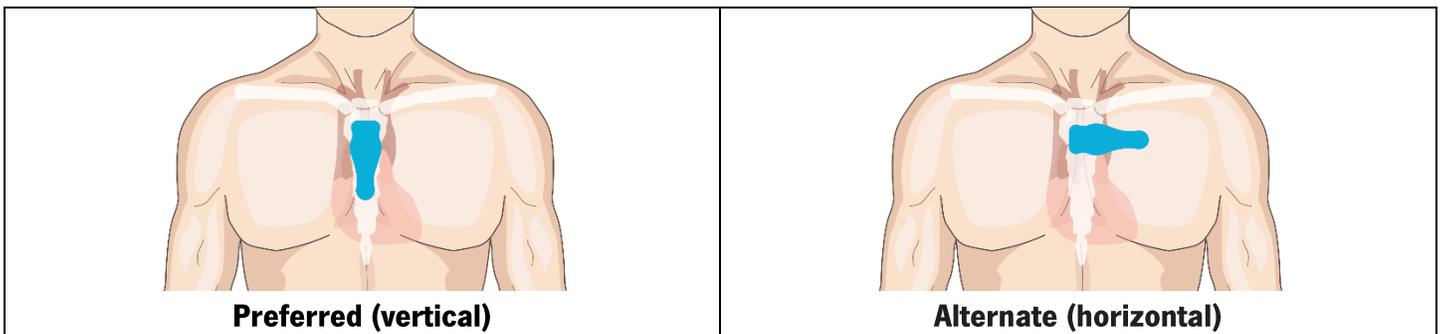
## Getting started (using Strips)

If your equipment came with Strips, use this section to attach your BodyGuardian Mini monitor to your chest and begin your monitoring prescription.

- If your equipment came with a **Bridge**, see **page 11**.
- If your equipment came with an ECG lead set, see **page 17**.

### 1 Prepare your skin

You can wear the BodyGuardian Mini Slide Strip either vertically or horizontally.

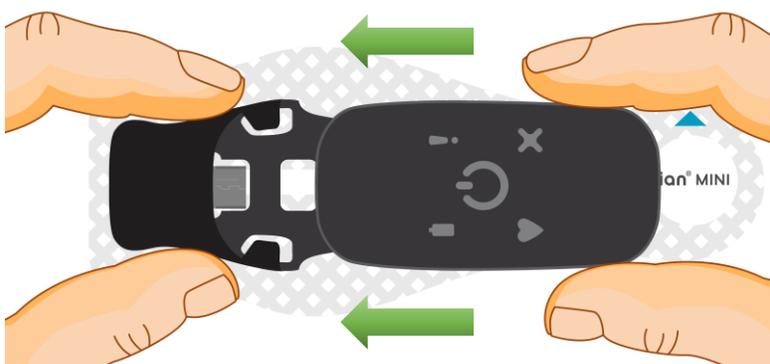


Decide which chest placement you will use before you prepare your skin.

- If hair is present, remove the hair where you will place the monitor.
- Use either the enclosed saline wipe or soap and water to clean the area. Dry the area completely.
- Do not apply lotions, oils, or perfumes. Do not use alcohol.

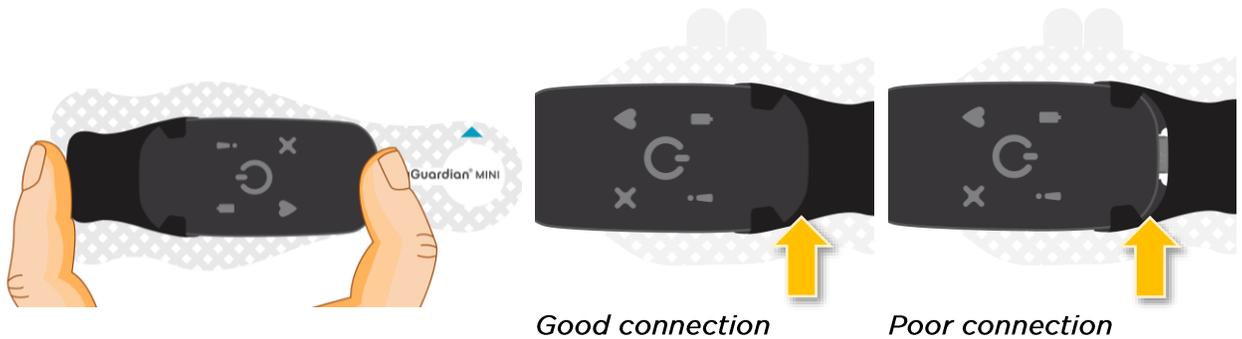
### 2 Attach the monitor to the Strip

1. Slide the monitor into the black molding on the Strip until the micro-USB connector on the Strip is inserted completely into the monitor.



**Tips**

- This is most easily accomplished on a flat surface, like a table.
- To line up the micro-USB connector with the port on the monitor, you may need to wiggle the monitor slightly to align.
- To ensure a good connection, pinch together with thumb and index finger:

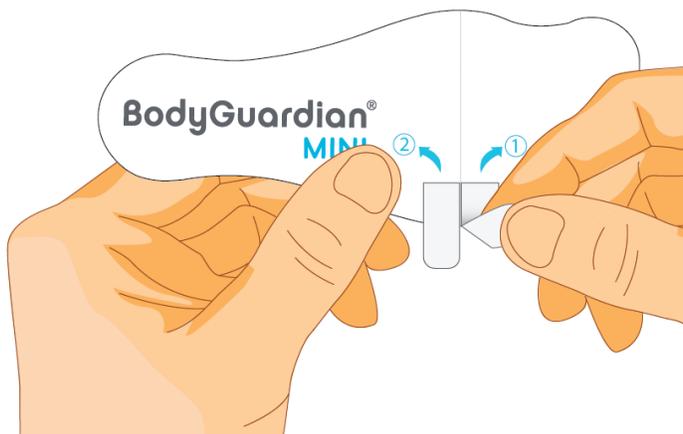


**3 Attach to your chest**



Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the most appropriate option.

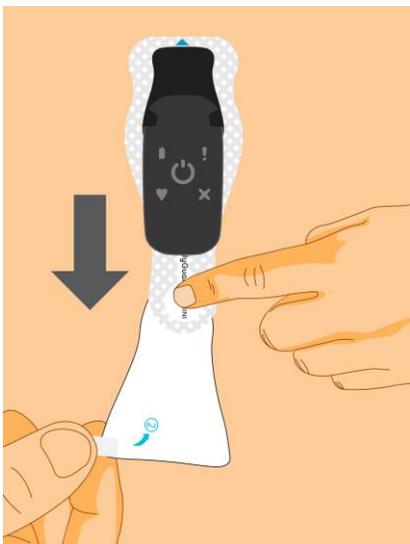
1. Peel away backing **1** from the Strip.



2. Place the portion of the Strip with the adhesive exposed flat on your chest in one of the placement locations (see pages 8-9).



3. Slowly peel away backing **2** from the Strip as you press the Strip flat on your chest. Press the entire surface of the Strip against the skin to ensure it adheres.



Do not wrinkle the Strip.

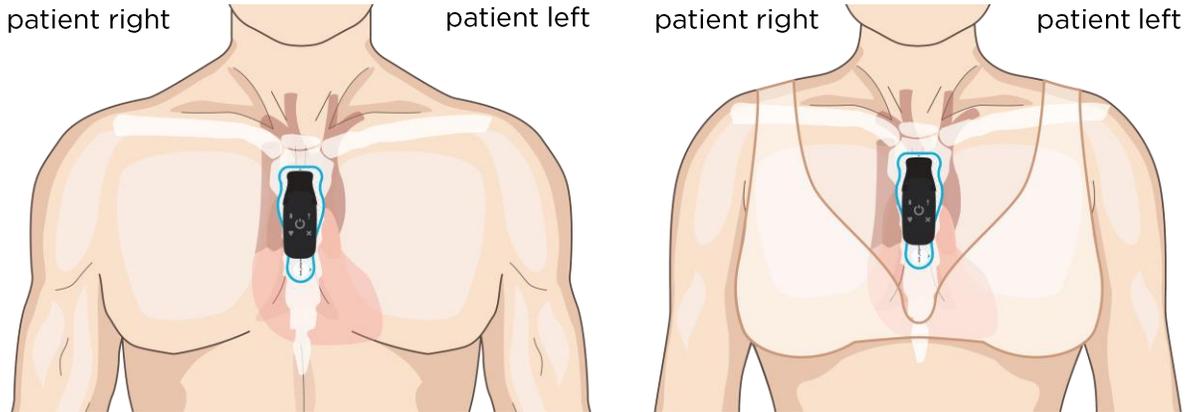


Do not tuck or pin Strip

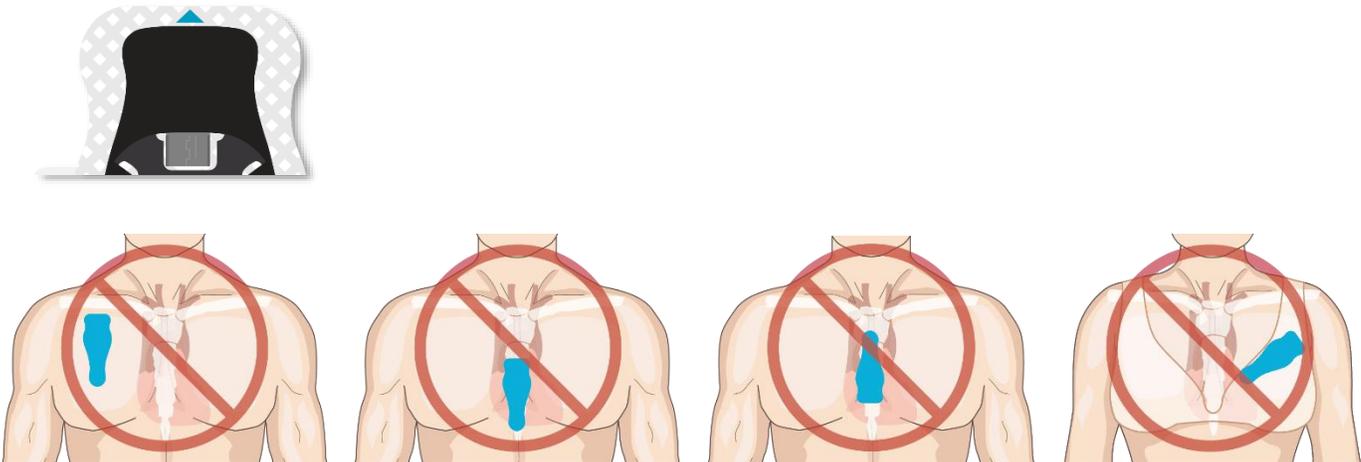
### Preferred chest placement (vertical)

 Once the Strip makes contact with your skin, you cannot adjust its position.

Place the top of the Strip just below the jugular notch, which is the bone at the base of the neck at the intersection of the collar bone.



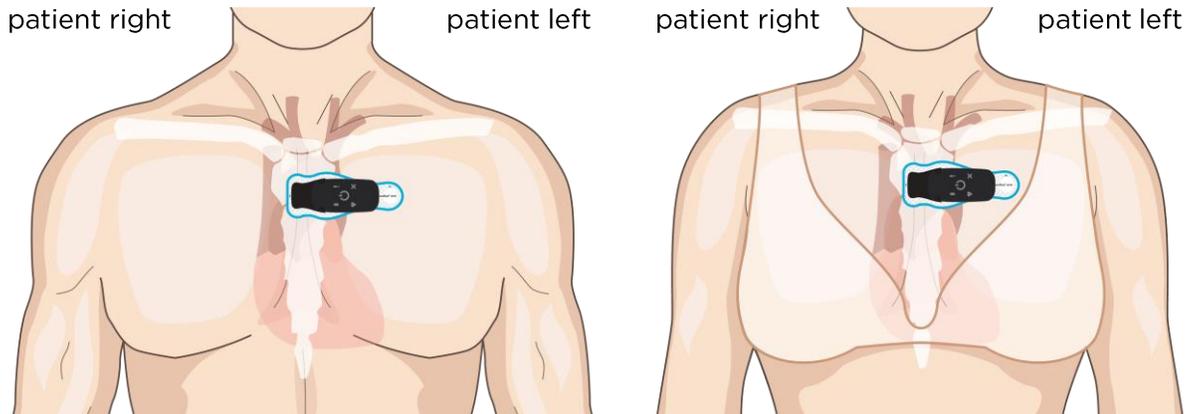
Ensure the uppermost arrow on the Strip on your chest is pointing up.



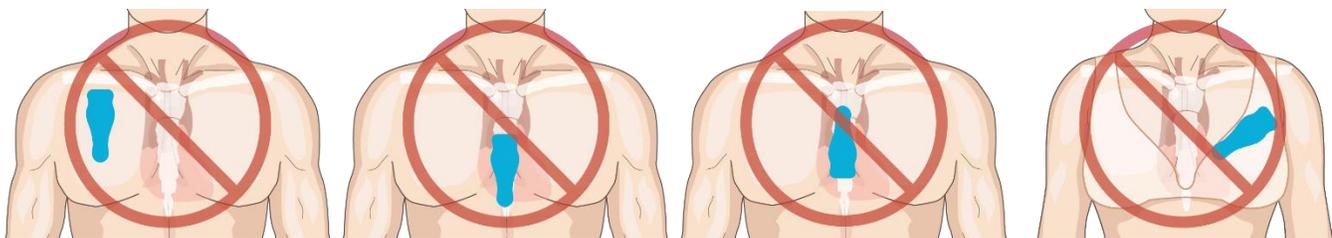
### Alternate placement (horizontal)

 Once the Strip makes contact with your skin, you cannot adjust its position.

Place the right side of the Strip near the center of the chest over the sternum.



Ensure the arrow on the Strip over your left chest, near your left arm, is pointing up.



## 4 Turn on monitor

Press and release the center button on the monitor once.

### If contact between the Strip and your skin is satisfactory:

The monitor makes a quick series of three rising beeps and the green light blinks every 5 seconds. You are successfully monitoring.

### If contact between the Strip and your skin is NOT satisfactory:

The monitor alerts you with two beeps every second. If this occurs:

1. Revisit the previous steps in this manual to ensure that:
  - The monitor is securely attached to the Strip.
  - BodyGuardian Mini is properly placed and securely adhered to your chest.

When the monitor detects satisfactory skin contact, it will make a quick series of three rising beeps and the green light blinks every 5 seconds. **You are successfully monitoring.**

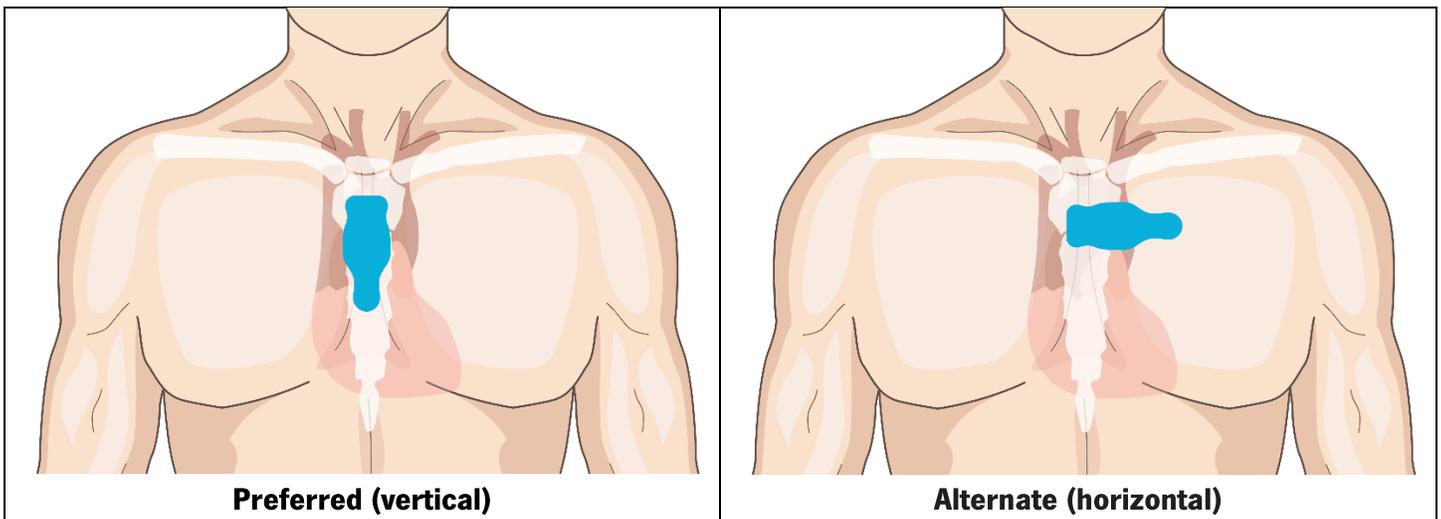
## Getting started (using a Bridge)

If your equipment came with a Bridge, use this section to get your BodyGuardian Mini monitor attached to your chest and begin your monitoring prescription.

- If your equipment came with **Strips**, see **page 5**.
- If your equipment came with an **ECG lead set**, see **page 17**.

### 1 Prepare your skin

You can wear the BodyGuardian Mini Bridge either vertically or horizontally.

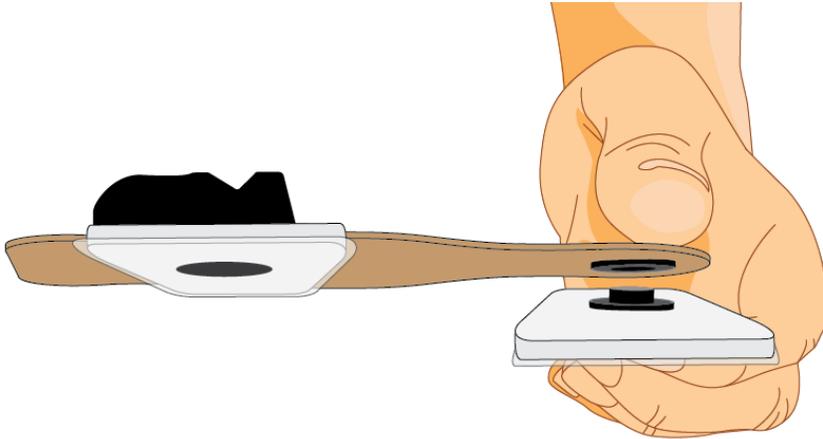


Decide which chest placement you will use before you prepare your skin.

- If hair is present, remove the hair where you will place the monitor.
- Use soap and water to clean the area. Dry the area completely.
- Do not apply lotions, oils, or perfumes. Do not use alcohol.

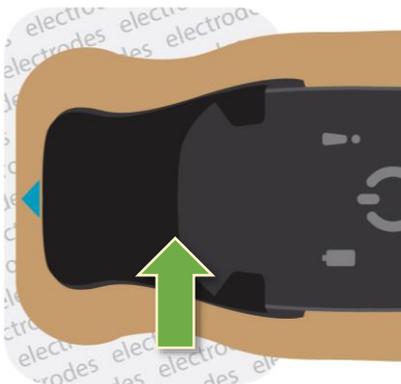
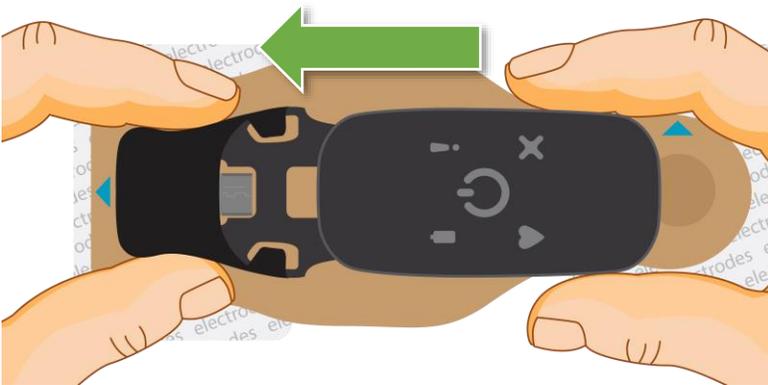
## 2 Snap the ECG electrodes to the Bridge

1. Press the ECG electrodes firmly onto the Bridge until you hear a snap.

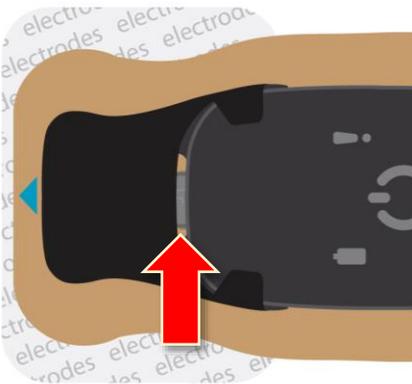


## 3 Attach the monitor to the Bridge

Slide the monitor into the black molding on the Bridge until the micro-USB connector is inserted completely into the monitor.



*Good connection*



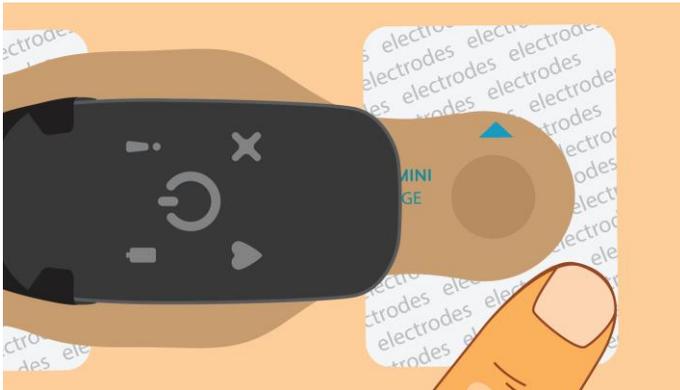
*Poor connection*

## 4 Attach to your chest



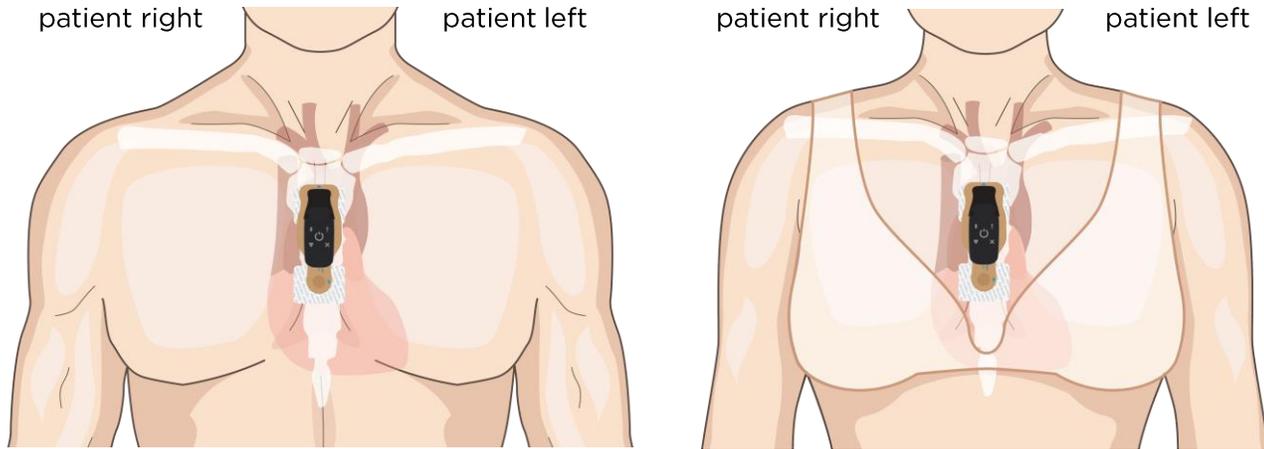
Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the most appropriate option.

1. Peel away backing from the electrodes to expose the adhesive.
2. Place on chest in one of the placement locations (see [pages 14-15](#)).
3. Press firmly around the surface of the electrode to ensure adhesion to the skin.

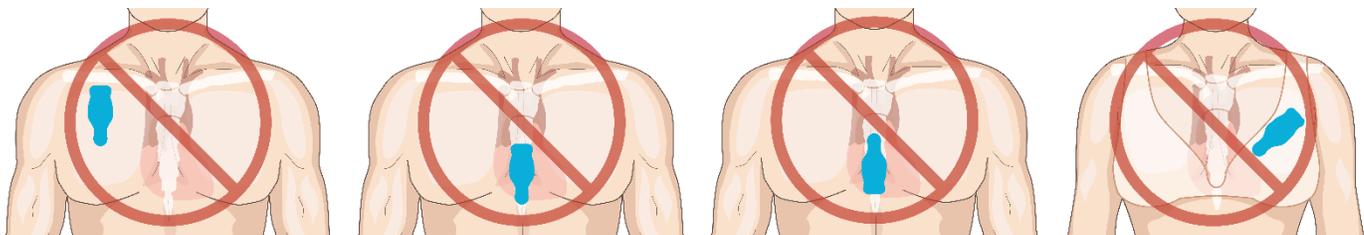


**Preferred chest placement (vertical)**

Place the top of the Bridge just below the jugular notch, which is the bone at the base of the neck at the intersection of the collar bone.

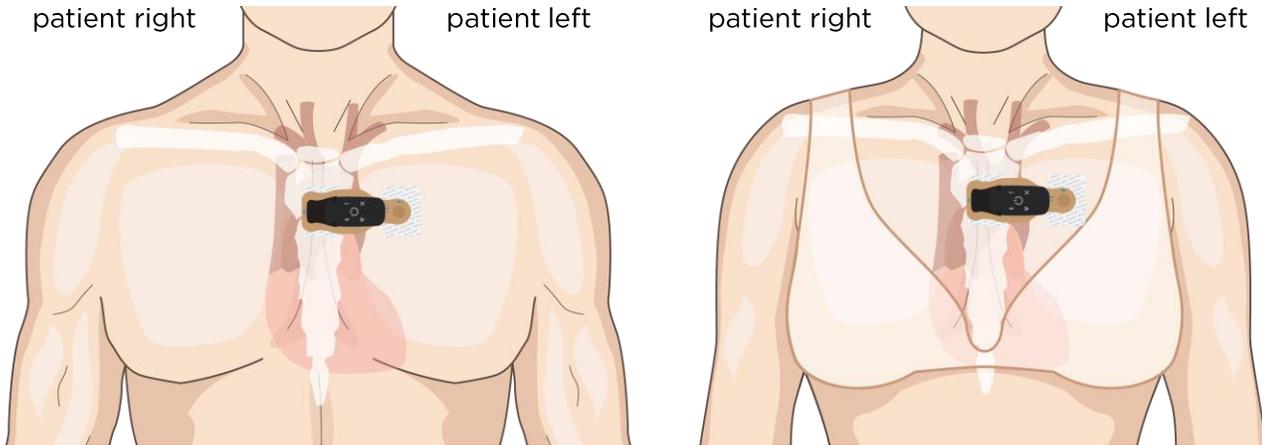


Ensure the uppermost arrow on the Bridge on your chest is pointing up.

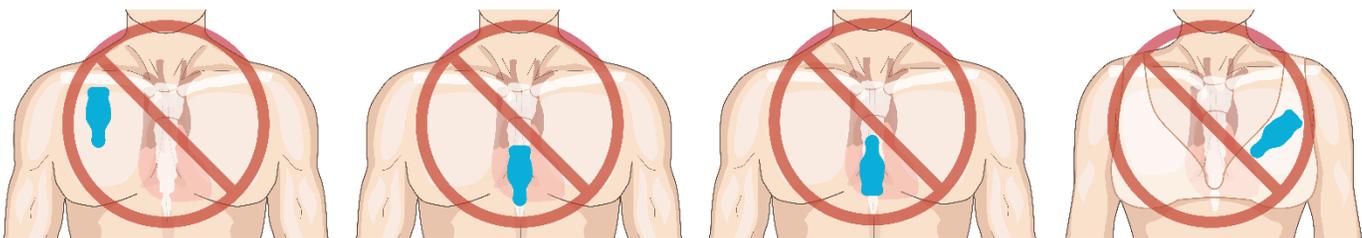


**Alternate placement (horizontal)**

Place the right side of the Bridge near the center of the chest over the sternum.



Ensure the arrow on the Bridge over your left chest, near your left arm, is pointing up.



## 5 Turn on monitor

Press and release the center button on the monitor once.

**If contact between the electrodes and your skin is satisfactory:**

The monitor makes a quick series of three rising beeps and the green light blinks every 5 seconds. You are successfully monitoring.

**If contact between the electrodes and your skin is NOT satisfactory:**

The monitor alerts you with two beeps every second. If this occurs:

1. Revisit the previous steps in this manual to ensure that:
  - The monitor is securely attached to the Bridge.
  - BodyGuardian Mini Bridge is properly placed and securely adhered to your chest.

When the monitor detects satisfactory skin contact, it will make a quick series of three rising beeps and the green light blinks every 5 seconds. **You are successfully monitoring.**

---

## Getting started (using an ECG lead set)

If your equipment came with an ECG lead set, use this section to get your BodyGuardian Mini monitor attached to your chest and begin your monitoring prescription.

- If your equipment came with **Strips**, see **page 5**.
- If your equipment came with a **Bridge**, see **page 11**.

### 1 Prepare your skin

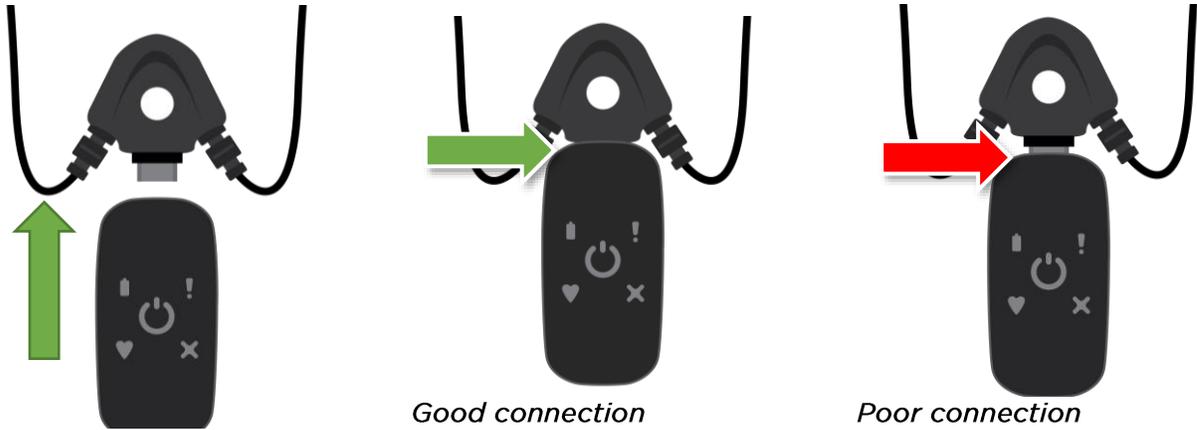
Familiarize yourself with the three chest locations where you will attach ECG electrodes.

See **Attach to your chest** on page 18 for the chest locations where you will place the monitor and ECG electrodes.

- If hair is present, remove the hair where you will place the ECG electrodes.
- Use soap and water to clean the area. Dry the area completely.
- Do not apply lotions, oils, or perfumes. Do not use alcohol.

## 2 Attach the monitor and the ECG electrodes

- Slide the monitor onto the center connector of the lead wires. Ensure the connector is inserted completely into the monitor.



2. Snap an ECG electrode into each of the leads and one into the center monitor connector.

## 3 Attach to your chest

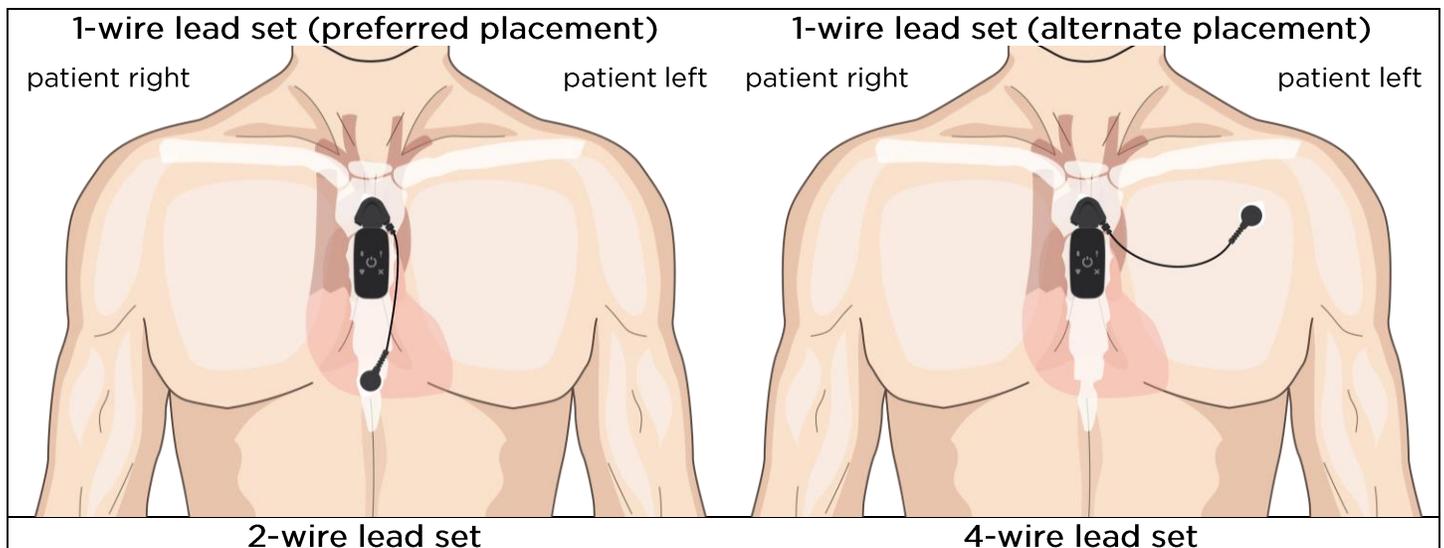


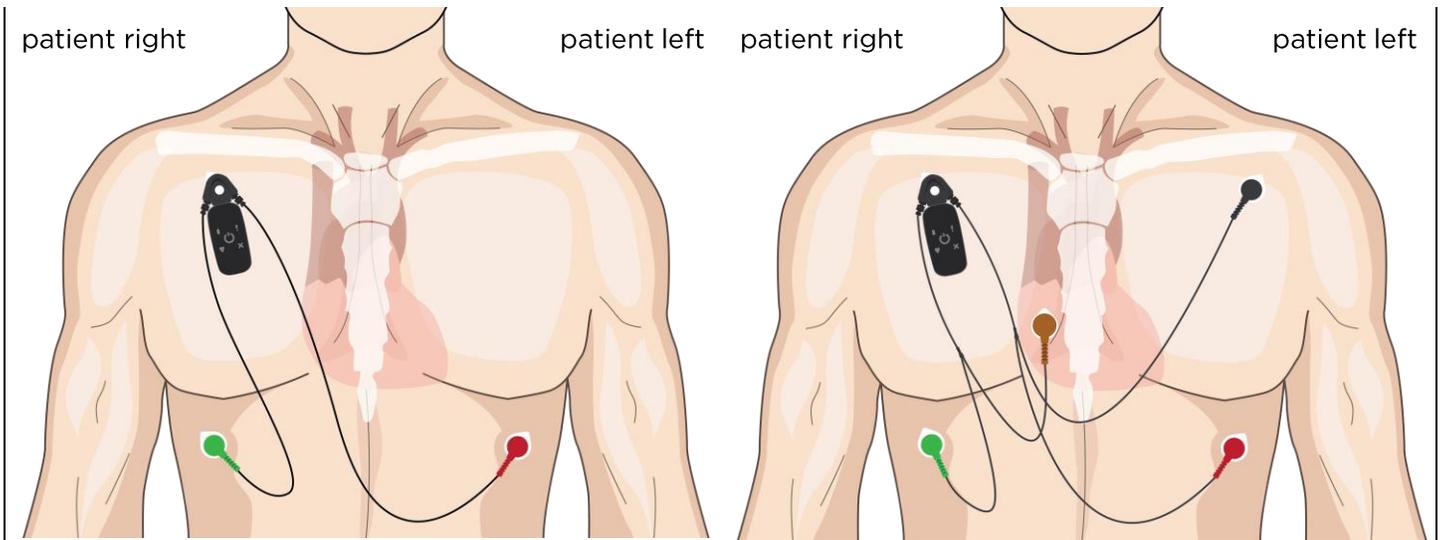
Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the most appropriate option.

Remove the adhesive backing from each of the electrodes, then attach them to the following locations:

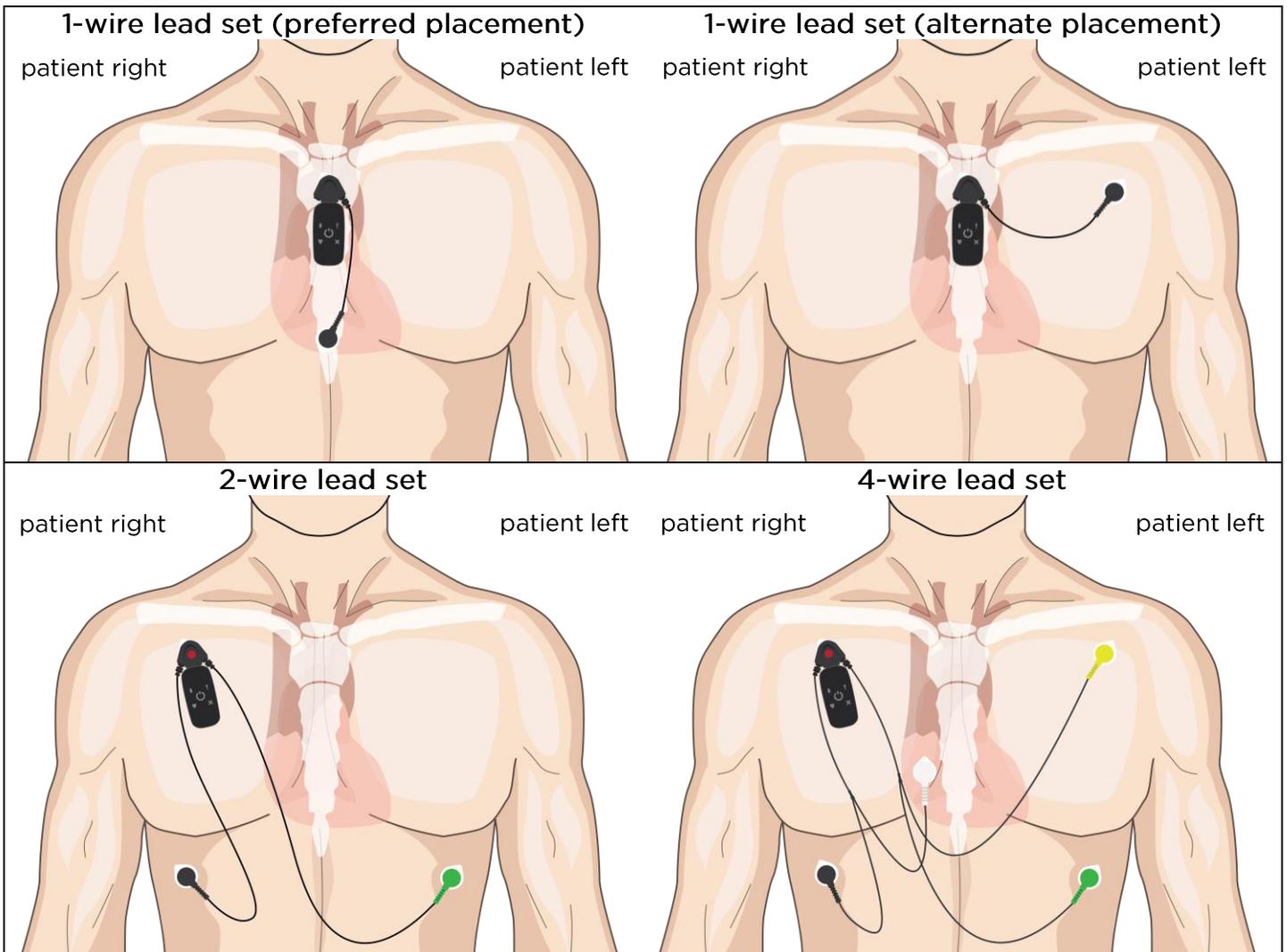


For patients in the EU, see EU chest placements on page 19.





**EU chest placements**



## 4 Turn on monitor

Press and release the center button on the monitor once.

**If contact between the ECG lead set and your skin is satisfactory:**

The monitor makes a quick series of three rising beeps and the green light blinks every 5 seconds. You are successfully monitoring.

**If contact between the ECG lead set and your skin is NOT satisfactory:**

The monitor alerts you with two beeps every second. If this occurs:

1. Revisit the previous steps in this manual to ensure that:
  - The monitor and leads are securely attached to the ECG electrodes.
  - BodyGuardian Mini is properly placed and securely adhered to your chest.

When the monitor detects satisfactory skin contact, it will make a quick series of three rising beeps and the green light blinks every 5 seconds. **You are successfully monitoring.**

---

## Recording symptoms

If you begin to feel symptoms related to the reason your monitor was prescribed, such as dizziness, chest pain, or shortness of breath, you can manually record these events.

1. On the monitor, press and release the center button once. The monitor makes a single beep on a successful button push. Do not hold the button down.
2. In your Holter diary, write down the symptom date and time.
3. Check the symptoms you are feeling.
4. Check the activity you were doing at the time you felt the symptom(s).

**Note:** Be sure to include your diary in the box when you return your equipment at the conclusion of your prescription.

## Charging the monitor

When the monitor battery is low, the monitor alerts you with two beeps and blue blinks every 5 seconds. If the low battery alert sounds, charge the monitor immediately.

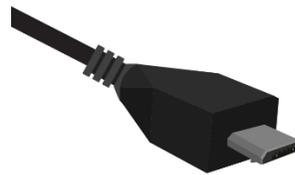


Do not use your own personal device chargers. Only use the charger(s) provided to charge Boston Scientific Cardiac Diagnostics devices.

1. Remove BodyGuardian Mini from your chest:
  - a. **If you are using Strips**, remove the Strip from your chest, then remove the monitor from the Strip.
  - b. **If you are using a Bridge**, remove the Bridge and electrodes from your chest, then remove the monitor from the Bridge.
  - c. **If you are using an ECG lead set**, remove the electrodes from your chest, then remove the monitor from lead set.
2. Plug the charging cord into the monitor. Ensure the other end is plugged into a wall outlet.

### Important

Ensure the micro-USB connector is oriented this way when inserting into the monitor.



front view



side view

3. As soon as the monitor is fully charged, use a *new* Strip or *new* electrodes to re-apply BodyGuardian Mini to your chest.
4. Press and release the center button on the monitor to power it on.
  - Do not hold the button down.

## Charging time



- **While charging**, the blue light on the monitor blinks.
- **Once fully charged**, the blue light on the monitor remains solidly lit.
- **Charging time**: 1.5-2.5 hours

---

## Replacing the Strip

If your equipment came with Strips, change the Strip on your chest when it no longer adheres to the skin. Strips are disposable.



To protect signal quality, it's important to not expose the monitor's micro-USB connector directly to water.

1. Remove the monitor from the Strip, then charge the monitor.
2. Slowly peel back and roll the adhesive away from your chest, continually blotting with lukewarm soapy water.  
**Tip:** For easiest removal, start by peeling back the edge of the Strip furthest from the black hub. It is suggested to remove the Strip while showering to limit the potential for skin irritation issues.
3. Use a *new* Strip to re-attach BodyGuardian Mini to your chest.

---

## Replace the ECG electrodes (for Bridge or ECG lead set)

If your equipment came with a Bridge or ECG lead set, change the ECG electrodes on your chest every 3 days OR when they no longer adhere to the skin. Electrodes are disposable.

1. Remove the electrodes while showering or use a warm, damp cloth to blot while removing. Slowly peel back and roll the adhesive on the back of the electrodes away from your chest.
2. Remove the leads from the electrodes.
3. Remove the monitor from the center connector, then charge the monitor.
4. Use *new* ECG electrodes to re-attach BodyGuardian Mini to your chest.

---

## Water resistance

The accessories (Strips, Bridge, and ECG lead set) are waterproof and can safely be submerged in water as deep as 3 feet.

The monitor is waterproof when plugged into a body-worn accessory that **does not** leave the micro-USB port exposed. The micro-USB port should **not** be exposed to water.

- You do not need to remove BodyGuardian Mini when showering or bathing.
- If you will be swimming in water deeper than 3 feet, remove the monitor.
- If micro-USB connector on an unattached monitor is exposed to water, open air dry for at least 1 hour before reattaching to a Strip, lead set or charger.

After showering, bathing or swimming while wearing BodyGuardian Mini with a Strip:

- Pat the Strip with a towel to dry it off.
- Press and hold the Strip against your chest to ensure good contact with your skin.

---

## Air travel

BodyGuardian Mini is safe to wear while traveling on aircraft. You do not need to remove the monitor.

---

## Cleaning the monitor

### Exterior casing

1. Monitor shall be cleaned with PDI AF3 Sani-Cloth wipes, Mikrozid® Alcohol Free Wipes (available in the EU), equivalent alcohol-free/bleach-free wipes or a mild detergent solution by gently wiping down all surfaces using a soft cloth. The cleaning surface must be visibly clean. Once visibly clean (visible dirt and debris is removed), the cleaning surface must be kept wet with the cleaning solution for the specified time to ensure all potentially contaminating pathogens are neutralized and removed as follows:
  - a. **PDI AF3 Sani-Cloth wipes:** minimum of three (3) minutes solution contact for as per the manufacturer's instructions.
  - b. **Mikrozid Alcohol Free Wipes (available in the EU):** minimum of one (1) minute solution contact for as per the manufacturer's instructions.
  - c. if an alternate alcohol-free/bleach-free cleaning solution is used, the manufacturer's recommended cleaning instructions shall be followed.
  - d. if a mild detergent solution is used, gently rub with a soft cloth for a minimum of one to two (1-2) minutes.
2. Ensure excess cleaning solution does not collect in the device micro-USB connector, and do not submerge the equipment.
3. Allow the monitor to air dry. **NOTE:** Typical dry time is within 3 minutes. Allow for longer dry time if solution collects in the micro-USB connector.

### USB port

To help ensure quality ECG signal, the monitor's USB port should be cleaned upon completion of each patient study. These cleaning steps can be incorporated into existing cleaning processes.

### Required materials

- Nitrile gloves or equivalent
- Safety glasses
- Microfiber or polyester lint free cloth
- High Purity Isopropyl Alcohol (IPA) (99%) with dispenser
- Small diameter swabs (use one per device)



Swab selection is critical to both effectively clean the connector and also prevent damage to the device connector.

It is recommended to order and use one of the following swabs for connector cleaning:

1. Cleansky Part Number CK-FS757
2. Techspray Optic Techswab (1.25mm)
3. SHENDU-1197 swab
4. A swab with substantially equivalent attributes and size to effectively clean the micro-USB connector:
  - a. Swab with a thin and soft material-covered tip (such as foam)
  - b. **Head Length** of 7.0mm – 14.0mm (0.28 inches - 0.55 inches)
  - c. **Head Width** of 1.0mm – 4.5mm (0.04 inches – 0.18 inches)
  - d. **Head Thickness** of 1.0mm – 2.6mm (0.04 inches – 0.10 inches), including foam. When compressed the thickness shall not exceed 1.25mm (0.05 inches).

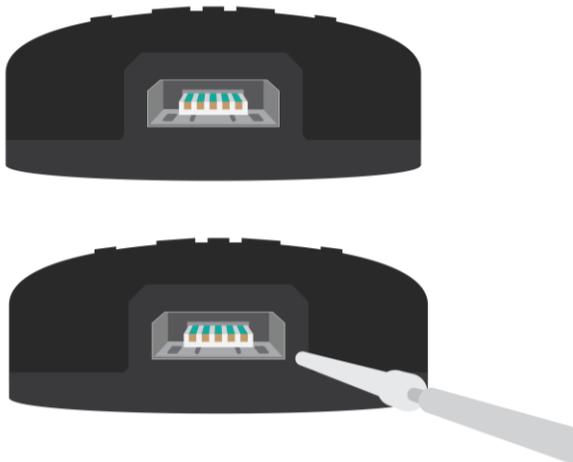


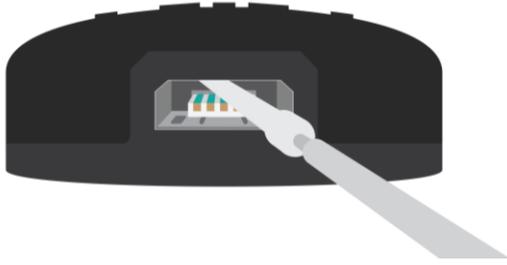
Using products other than those specified to clean the monitor connectors on your BodyGuardian MINI may result in damage to the USB port and/or the connectors voiding the warranty. Avoid sharp or abrasive tools that could scratch or bend the connector pins.

## Cleaning the USB port

1. Saturate swab material with High Purity Isopropyl Alcohol (IPA), then flex and rotate the tip of swab back and forth across the USB pins. This action shall occur for at least 10 seconds. Scrub any corroded interior surfaces to remove as much corrosion as possible.

**Note:** Do not touch the black monitor casing with the IPA solution. If the IPA solution does come into contact with the casing, wipe with a lint free cloth as soon as possible.





2. Once the cleaning process is complete, allow the monitor to air dry for a minimum of 20 minutes before using the monitor (including recharging). You can tap the device upside down on the microfiber or polyester lint free cloth which will aid in allowing excess High Purity Isopropyl Alcohol (IPA) to drip out of the USB port. Ideally, the scrubbing process will remove any substantial amount of corrosion from the connector.

---

## If the monitor starts beeping during your monitoring session

### 2 beeps and 2 red flashes every 5 seconds



BodyGuardian Mini has not detected good contact with your skin for over 8 hours.

#### RESOLUTION

Revisit the previous steps in this manual to ensure that:

- The monitor is securely attached to the Strip or ECG lead set.
- BodyGuardian Mini is properly placed and securely adhered to your chest.
- If the monitor continues to beep:
  - Remove the Strip or ECG electrodes, use a new Strip or ECG electrodes, and repeat the setup steps.

### 2 beeps and 2 blue flashes every 5 seconds



Your monitor battery is low.

#### RESOLUTION

Charge the monitor immediately.

## Monitor indicators

This section explains the sounds and LED lights on the monitor.

If you are curious about what the monitors sounds and lights mean, you can use this information as a reference.

**Note:** The monitor lights are faint. They can best be detected in a dark or dimly lit room

Sounds	Lights	What it means	Caused by
 and 	every 1 sec	Poor skin contact.	Monitor cannot detect good skin contact with skin to begin monitoring.
none		every 5 sec	Poor skin contact. Monitor cannot detect good contact with skin during already established monitoring session. If this persists for 30 minutes or more, replace your Strip, Bridge or electrodes.
 and 	every 5 sec	Poor skin contact.	Monitor has not detected good contact with skin for over 8 hours. Replace your Strip or electrodes.
none		Charging issue.	Battery charge not reaching target level in pre-defined time.
 and 	every 5 sec	Monitor battery is low.	Low monitor battery. Charge the monitor.
none and 	every 5 sec	Monitoring successfully.	
	none	Symptom marked.	Press-and-release button push.
 and 		Monitor is powering on.	Press-and-release button push.
	   	Monitor is powering off.	Press-and-hold (10-12 sec) button push.

*After 10-12 seconds, all four monitor lights flash once, followed by a long beep.*

---

## Contraindications

### System Level

The BodyGuardian Mini (in the EU called BodyGuardian Mini Procedure Pack) is not intended to provide diagnoses. The web portal and reports should not be used without supervision and review by a qualified physician.

The BodyGuardian System and BodyGuardian Mini Monitor is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

---

## Warnings

### System Level

- Do not attempt self-diagnosis or self-treatment based on acquired data.
- Patients with known skin allergies or hypersensitivities to adhesives or hydrogel may experience reactions. Patients should consult with their health care professional to select a Strip or alternate electrode option that is most appropriate for their needs.
- Use BodyGuardian Mini with accessories provided by Boston Scientific Cardiac Diagnostics. Other cables and accessories may negatively affect sensor performance.

### BodyGuardian Mini Monitor

- The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator.
- Patients who have active implantable medical device (like heart pacemaker and so on), should consult supervising physician or doctor before use.
- Do not touch parts of the computer, docking station or any non-medical electrical equipment and the patient at the same time when operating the monitor.
- To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the monitor should comply with IEC/EN 60950 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfils the requirements.
- EMC disturbances might cause interference and/or noise to data acquisition
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by Boston Scientific Cardiac Diagnostics, Inc. Otherwise, degradation of the performance of this equipment could result.

---

## General safety precautions

### System Level

- United States federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.
- Always follow instructions for disposable electrodes which are used for recordings.
- Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas.
- Do not use lotions, oils, or sprays on skin location where you will apply the Strip.
- The procedure pack is for single patient use only.

### BodyGuardian Mini Monitor

- Use ECG sampling rate of 500Hz with pediatric patients weighing less than 10 kg.
- The monitor IP Classification code is 67 when used with the strip. When used underwater or showering with bridge or lead set, the system is safe to wear on-body; however, data output will be temporarily affected. When the monitor is disconnected and exposed to water, the IPX rating is 0.
- Do not disassemble, try to repair, or modify monitor.
- Monitor does not have any electrical stimulation capabilities.
- Monitor does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation.
- Accelerometer data is not analyzed within the monitor or differentiated between various physical activities.
- Operating environments: Professional healthcare facility environment and Home healthcare environment.
- If a patient has been given defibrillation, while the monitor and applied part are connected to the patient, the monitor and applied part must be sent to manufacturer for checking before continuing device use.
- BodyGuardian Mini cannot be worn while undergoing an MRI.
- Do not use a monitor if the casing is broken or damaged.
- Do not dispose of the monitors. Return monitors to your health care provider.

#### Notice to User and/or Patient:

Any serious incident that has occurred in relation to this device should be reported to Boston Scientific Cardiac Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

## Appendix A: Symbols

Symbol	Description
	The Mini monitor is CE-marked for the conformity to Council Directive 93/42/EEC regarding medical devices.
	Medical device.
	The Mini monitor is equipped with type BF applied parts fulfilling the EN 60601-1 (IEC60601-1) standard.
	The additional electrodes are disposable.
	Consult Instructions For Use.
	The Lot number of the electrodes.
	For EU only: This symbol indicates that this device shall be disposed according to European Union directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).
	During transportation: keep package dry, protect from rain.
NOTE!	Note text in manual: These statements identify conditions or practices that could result in equipment performance loss or must be otherwise observed.
IP67	IP classification for device. The monitor is waterproof while recording is made with lead set, the Bridge or the Strip fixed to device or with electrode fixed to device. The device is safe although the output is temporarily affected when using the Bridge or lead set during exposure to water, in which case the IP classification is temporarily IPX0 during water exposure.
	This equipment contains specified radio equipment that has been certified to the Technical Regulation Conformity Certification under the Radio Law. Bluetooth module BT121 is certified in Japan with certification number 209-J00171
	Wireless Transmission Symbol.

	<p>A relative humidity range of 15 % to 90 %, non-condensing</p>
	<p>Transport and storage conditions                  -20 °C to + 60 °C (transport)                  -20 °C to + 60 °C at a relative humidity up to 90 %, non- condensing (storage)</p>
<p><b>REF</b></p>	<p>Indicates the catalogue number so that the medical device can be identified</p>
	<p>Manufacturer</p>
	<p>Warning: MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment</p>
	<p>A data matrix (GS1) code is a two- dimensional barcode consisting GTIN and PI for ECG sensor</p>

## Appendix B: Technical specifications

1-channel ECG	Yes
ECG sampling frequency	250 Hz
ADC precision	24 bits
Input Impedance	>10.1Mohms +/- 0.1Mohm
Datalogger file format	EDF
Memory capacity	4 GB
Power source	3,7 V Li-ion battery
Dimensions (SL)	48 x 29 x 12 (mm) Weight 18 g
Dimensions (EL)	59 x 30 x 13 (mm) Weight 22 g
Operating time (SL)	Up to 8 days
Operating time (EL)	Up to 16 days

Boston Scientific Cardiac Diagnostics reserves all rights to improve, change and modify the products and the contents of the Instructions for Use without prior notice.

## Appendix C: Electromagnetic Emission

Manufacturer's Declaration - Electromagnetic Emissions		
BodyGuardian Mini is suitable for use in an electromagnetic environment as described below. The users should ensure that the device is used in such an environment.		
Emission Tests	Compliance	Electromagnetic Environment
RF emissions CISPR11	Group 1	The monitor uses RF energy exclusively for its internal function. Thus, the RF emission is very low, and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR11	Class B	

## Appendix D: Immunity Test Levels

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Appendix 2	
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	Not applicable	
Voltage interruptions	IEC 61000-4-11	Not applicable	
Surges Line-to-line	IEC 61000-4-5	Not applicable	
Surges Line-to-ground	IEC 61000-4-5	Not applicable	
Electrical fast transients / bursts	IEC 61000-4-4	Not applicable	

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 -390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						



**EMERGO EUROPE**  
 Westervoortsedijk 60  
 6827 AT Arnhem, The Netherlands



**MEDENVOY**  
 Gotthardstrasse 28  
 6302 Zug, Switzerland

**EMERGO CONSULTING (UK) LIMITED**  
 c/o Cr360 -UL International  
 Compass House, Vision Park Histon  
 Cambridge CB24 9BZ United Kingdom



**BODYGUARDIAN MINI MONITOR**  
**Bittium Biosignals Ltd**  
 Pioneerinkatu 6  
 70800 Kuopio  
 Finland



**PATIENTCARE PLATFORM**  
 (not included in pack)  
**Boston Scientific Cardiac Diagnostic Technologies, Inc.**  
 2900 37<sup>th</sup> Street NW  
 Building 003  
 Rochester, MN 55901  
 USA



**PATIENTCARE LINK**  
 (not included in pack)  
**Boston Scientific Cardiac Diagnostic Technologies, Inc.**  
 2900 37<sup>th</sup> Street NW  
 Building 003  
 Rochester, MN 55901  
 USA



**BODYGUARDIAN MINI SLIDE STRIP**  
 (optionally included in pack)  
**Boston Scientific Cardiac Diagnostic Technologies, Inc.**  
 2900 37<sup>th</sup> Street NW  
 Building 003  
 Rochester, MN 55901  
 USA



**BODYGUARDIAN MINI BRIDGE**  
 (optionally included in pack)  
**Boston Scientific Cardiac Diagnostic Technologies, Inc.**  
 2900 37<sup>th</sup> Street NW  
 Building 003  
 Rochester, MN 55901  
 USA



**ASSEMBLED &  
 DISTRIBUTED  
 FOR:**

**Boston Scientific Cardiac Diagnostic Technologies, Inc.**  
 2900 37<sup>th</sup> Street NW  
 Building 003  
 Rochester, MN 55901  
 USA

For manufacturer comments or concerns: 507-218-3437